In addition to its failure to satisfy the most basic pleading requirement, plaintiff also fails to satisfy the minimum Rule 9(b) standard articulated by this Court. Specifically, in contravention of the Court's Order, the Complaint here does not "clearly and concisely" state "the allegedly *fraudulent* AWP for each drug." Order at 45 (emphasis added). Under the Court's test, it is not enough to simply list, as plaintiff has done, a drug's published AWP and an "Estimated Overcharge" based on an unexplained "True AWP." Conclusory allegations based on a simple regurgitation of the published AWP juxtaposed against some mathematical calculation designed to elicit an estimated overcharge, without even noting any of the assumptions behind the calculations, much less specific facts that constitute fraud, do not satisfy the Court's requirement that a *fraudulent* AWP be alleged. Not a single fact in the Complaint details any instance of fraudulent Sanofi activity connected with the reporting of AWPs, WACs, AMPs, or "best prices." Indeed, as noted above, the Complaint does not even allege that Sanofi set the AWPs, WACs, AMPs or "best prices" for any drug. To the extent that plaintiff truly conducted the "investigation" it claims forms the basis for its calculated overcharges, *see* Compl. ¶7, it is required to have set forth at least some specific conduct by Sanofi. As this Court has noted, the law precludes "conclusory allegations of fraud from serving as a basis for strike suits and fishing expeditions." *United States ex rel. Franklin v. Parke-Davis*, 147 F.Supp.2d 39, 46 (D. Mass. 2001) (Saris, J.).[6]

**B. Plaintiff Fails To Allege RICO Predicate Acts With Particularity.**

Plaintiff's RICO claims are based on an alleged pattern of racketeering activity involving mail and wire fraud. The Complaint, however, fails to provide a single example of mail or wire

[6] Plaintiff also fails to allege fraudulent concealment with the required specificity. *See Gonzalez-Bernal v. U.S.*, 907 F.2d 246, 250 (1st Cir. 1990). Thus, at a minimum, the Complaint and its attendant discovery obligations, should be limited to four years.

fraud perpetrated, or even participated in, by Sanofi. As held by the First Circuit, "[i]t is not enough for a plaintiff to file a RICO claim, chant the statutory mantra, and leave the identification of the predicate acts to the time of trial." *Feinstein v. Resolution Trust Corp.*, 942 F.2d 34, 42 (1st Cir. 1991). Plaintiff's broad and ambiguous references to "the defendants" – in an allegation that under Fed. R. Civ. P. 9(b) requires particular statement of the circumstances constituting fraud – fail to adequately plead a cause of action against Sanofi.

**II. Plaintiff's Claims Must Be Dismissed For Lack Of Standing.**

To satisfy the constitutional requirements for Article III standing, plaintiff must allege "personal injury fairly traceable to the defendant's allegedly unlawful conduct." Order at 41 (*quoting Allen v. Wright*, 468 U.S. 737, 751 (1984)). Here, it is impossible to tell, because of plaintiff's convoluted allegations, whether Suffolk or any of its citizens ever purchased any drug from Sanofi, and therefore whether it, or its citizens, has any "personal injury fairly traceable" to Sanofi. Because of this pleading deficiency, all of Suffolk County's claims against Sanofi should be dismissed for lack of standing. Order at 41.

In addition, as set out above, plaintiff has failed to allege any reasonably specific "unlawful conduct" undertaken by Sanofi -- no marketing on the "spread," no inducements, no instances of mail or wire fraud -- let alone conduct that can be fairly traced to Suffolk's alleged injury. For this reason, plaintiff should be found to lack standing as to Sanofi for all counts.

**CONCLUSION**

For the above reasons, as well as those set forth in Defendants' Consolidated Memorandum, plaintiff's claims against Sanofi should be dismissed with prejudice.

September 15, 2003

Respectfully submitted,

Colleen Hennessey /on

Colleen Hennessey
PEABODY & ARNOLD, LLP
50 Rowes Wharf
Boston, MA 02110
Telephone: (617) 951-2100
Facsimile: (617) 951-2125

Kevin R. Sullivan
Grace Rodriguez
Ann M. Malekzadeh
John D. Shakow
KING & SPALDING LLP
1730 Pennsylvania Avenue, N.W.
Washington, DC 20006
Telephone: (202) 737-0500
Facsimile: (202) 626-3737

Attorneys for Defendant Sanofi-Synthelabo Inc.

**MEMORANDUM OF SANOFI-SYNTHELABO INC.**
**IN SUPPORT OF ITS MOTION TO DISMISS**

**Exhibit A**

Three Paragraphs in the Complaint that Relate to Sanofi-Synthelabo, Inc. (*verbatim*)

49. Defendant Sanofi-Synthelabo, Inc. ("Sanofi") is a highly diversified health care corporation whose principal business was the development, manufacture and sale of health care products including pharmaceuticals. Sanofi's principal place of business is One Well Street, New York, New York 10286. Sanofi conducts extensive business in the State of New York, including in the County of Suffolk. Sanofi manufactures and /or sells prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County, including such medications as Plavix® and Ambien®.

268. Pfizer and its subsidiaries (Agouron and Sanofi-Synthelabo, Inc.), collectively referred to herein as the "Pfizer Defendants," routinely has reported or caused to be reported, inflated AWPs, resulting in overcharges to Suffolk. The specific drugs of the Pfizer Defendants for which relief is sought in this case are set forth in Exhibits A and B. Based on Suffolk's research, in 2001 alone, the Pfizer defendants reported false and inflated AWPs for the drugs at issue as follows:

| Drug | Reported Average Wholesale Price | Suffolk's Estimated True AWP | Estimated Overcharge | Estimated Overcharge as a percentage of Reported AWP |
|---|---|---|---|---|
| AMBIEN TAB 10MG | $2.69 | $2.03 | $0.66 | 25% |
| GLUCOTROL XL TAB 10MG | $0.83 | $0.63 | $0.20 | 24% |
| LIPITOR TAB 10MG | $2.39 | $1.61 | $0.77 | 32% |
| LIPITOR TAB 20MG | $3.64 | $2.42 | $1.22 | 34% |
| LIPITOR TAB 40MG | $3.64 | $2.39 | $1.26 | 34% |
| NEURONTIN TAB 300MG | $1.39 | $0.93 | $0.46 | 33% |
| NEURONTIN TAB 400MG | $1.67 | $1.15 | $0.52 | 31% |
| NEURONTIN TAB 600MG | $2.18 | $1.38 | $0.80 | 37% |
| NORVASC TAB 10MG | $2.17 | $1.47 | $0.70 | 32% |
| NORVASC TAB 5MG | $1.50 | $1.04 | $0.46 | 31% |
| ZITHROMAX TAB 250MG | $7.58 | $5.59 | $1.99 | 26% |
| ZOLOFT TAB 100MG | $2.65 | $1.85 | $0.79 | 30% |
| ZOLOFT TAB 50MG | $2.65 | $1.86 | $0.78 | 30% |
| ZYRTEC TAB 10MG | $210.95 | $132.88 | $78.07 | 37% |
| XALATAN 0.005% EYEDROPS | $53.38 | $39.15 | $14.23 | 27% |
| CELEBREX CAP 100MG | $1.58 | $1.19 | $0.39 | 25% |
| CELEBREX CAP 200MG | $2.76 | $1.93 | $0.83 | 30% |

341(v). *The Pfizer Defendants' Manufacturer-Publisher Enterprises*: The Pfizer Defendants' Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPs that were provided to them by the Pfizer defendants, and Pfizer, including its directors, employees and agents: (1) the Pfizer defendants-Thomson Medical Enterprise; (2) the Pfizer defendants-First DataBank Enterprise; and (3) the Pfizer-Facts & Comparisons Enterprise. Each of the Pfizer defendants Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, and (b) deriving profits from these activities. Each of the Pfizer Defendants' Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Pfizer and Thomson Medical, Pfizer and First DataBank, and Pfizer and Facts & Comparisons. As to each of these Pfizer Defendants' Manufacturer-Publisher Enterprises, the Pfizer Defendants' and each of Thomson Medical, First DataBank, and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Pfizer Defendants' Manufacturer-Publisher Enterprises was operated and conducted by the Pfizer Defendants' for criminal purposes, namely, carrying out the AWP Scheme.

# #15

**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

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|---|---|
| IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION | MDL No. 1456<br>Civil Action No. 01-CV-12257-PBS |
| THIS DOCUMENT RELATES TO:<br>*County of Suffolk v. Abbott Laboratories, Inc., et al.*, E.D.N.Y. Case No. CV-03-229 | Judge Patti B. Saris |

**MEMORANDUM OF SCHERING-PLOUGH CORPORATION IN SUPPORT OF THE MOTION TO DISMISS**

Schering-Plough Corporation ("Schering") moves to dismiss the Amended Complaint of the County of Suffolk ("County") pursuant to Fed. R. Civ. P. 12(b)(1), 12(b)(6) and 9(b). The Amended Complaint alleges that Schering engaged in two "types of wrongdoing" – the "fraudulent reporting of false and inflated average wholesale prices" and the "failure to report the 'Best Price'" – with respect to one of its drugs, Claritin Tab 10MG. Amended Complaint ¶¶ 2, 289, Exhibit A. The County's first charge founders on its own well-documented knowledge that AWP was nothing more than a sticker price and therefore fails to state a claim under any legal theory. The second charge must fail for the Amended Complaint's lack of a *single fact* relating to Schering's alleged failure accurately to report the best price. For these reasons, as well as those stated in Defendants' Memorandum of Law in Support of Their Motion to Dismiss the Amended Complaint ("Consolidated Memorandum"), all of the claims against Schering must be dismissed.

## ARGUMENT

### I. The State's Knowledge That AWP Was Merely a Sticker Price Defeats the Fraud-Based Claims as a Matter of Law

New York – like all states – has been warned for *decades* that AWP should not be used to establish reimbursement rates for state Medicaid programs. As detailed in the Consolidated Memorandum, the Office of the Inspector General ("OIG") of the Health Care Financing Administration ("HCFA") (now the Center for Medicare and Medicaid Services or "CMS") has warned states repeatedly that AWP is not a price that pharmacists and other purchasers of drugs actually pay. *See, e.g.*, HCFA Medicaid Transmittal, No. 84-12 (Sept. 1984) at 3 ("Pharmacies [actually] purchase drugs at prices that are discounted significantly below AWP or list price."); HS OIG Report, "Use of Average Wholesale Prices in Reimbursing Pharmacies in Medicaid and the Medicare Prescription Drug Program," (Oct. 1989), *reprinted in* Medicare & Medicaid Guide (CCH) ¶ 38,215 (1990) (noting that AWPs in industry publications overstate the prices that pharmacies actually pay by 10-20%). Indeed, HCFA formally disapproved the plans of those states that attempted to set Medicaid reimbursement rates at an undiscounted AWP. *Louisiana v. Dep't of Health & Human Servs.*, 905 F.2d 877 (5th Cir. 1990); *In re Arkansas Dep't of Human Servs.*, 1991 WL 634857 (HHS Dept. App. Bd. Aug 22, 1991); *In re Oklahoma Dep't of Human Servs.*, 1991 WL 634860 (HS Dept. App. Bd. Aug. 13, 1991). States have known for decades that AWP is not the price paid for prescription drugs.

The Amended Complaint confirms that, in setting its reimbursement rates, the State of New York acted with knowledge that AWP is not an actual price paid by providers. In fact, the County admits that New York does not reimburse Medicaid providers at AWP, but at AWP *minus* a significant percentage (now 12%). In light of the State's decision to reimburse at a significant discount off AWP, the County cannot honestly claim that it believed AWP

represented true wholesale prices for pharmacies, or that the publication of AWPs caused any actual harm to the County. It is readily apparent that the County's real claim is not that they were misled into believing that AWP represented actual wholesale prices, but that the State may have chosen the wrong discount off of AWP in estimating acquisition cost – a choice the State made without any input from manufacturers.

Given New York's admission that it *knew* that published AWPs were inflated and that it therefore *independently* established a reimbursement rate set at a discount off of AWP, the County's allegations of the "fraudulent reporting of false and inflated average wholesale prices" cannot state a claim as a matter of law.

## II. The Complaint Fails To Allege "Best Price" Claims Against Schering With Sufficient Particularity

The broad, general allegations that the defendants "routinely do not report the actual 'best price,'" and "utilized an array of other inducements to stimulate sales of their drugs" are wholly without substance and should be dismissed in their entirety. *See* Amended Complaint, ¶¶ 84-90, 290-292. Nowhere in its 400+ paragraph Amended Complaint does the County articulate a *single fact or example* to support its vacuous allegation concerning "Schering's failures to report Best Price as required by federal and state rebate statutes," Amended Complaint ¶ 290, or of any "other inducements" allegedly offered by Schering to providers. The Complaint does not identify even one drug for which Best Price was underreported, much less the "who, what, where and how" of Schering's alleged fraud that Rule 9(b) requires. *See United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 46 (D. Mass. 2001) (*quoting United States ex rel. Thompson v. Columbia/HCA Healthcare*, 125 F.3d 899, 903 (5th Cir. 1997)). Therefore, these allegations are insufficient under Rule 9(b) to "place [Schering] on notice and enable [it] to prepare meaningful responses." *New England Data Servs. v. Becher*, 829 F.2d 286, 289 (1st Cir. 1987).

Further, in this multidistrict litigation, the Court has also required plaintiffs to specify "the allegedly fraudulent price for the drug" in question. *In re Pharma. Indus. AWP Litig.*, 263 F. Supp. 2d 172, 194 (D. Mass. 2003). In Appendix A to the Amended Complaint, Plaintiff alleges only the 2001 AWP for Claritin Tab 10MG, as well as a figure identified as "Suffolk's Estimated True AWP." *See* Amended Complaint ¶ 75 & App. A. Plaintiff offers no explanation of how it arrived at this "True AWP." The allegation is inadequate to meet the pleading requirements of Rule 9(b).

## CONCLUSION

For the foregoing reasons, as well as those stated in the Consolidated Memorandum, Schering requests that it be dismissed from the Complaint, and that the dismissal be with prejudice.

Respectfully Submitted,

Original Signature On File With Court

John T. Montgomery (BBO#352220)
Brien T. O'Connor (BBO#546767)
Crystal D. Talley (BBO#633759)
John R. Therien (BBO#651185)
Ropes & Gray LLP
One International Place
Boston, Massachusetts 02110-2624
(617) 951-7000

Dated: September 15, 2003

CERTIFICATE OF SERVICE

I hereby certify that on September 15, 2003, I caused a true and correct copy of the Memorandum of Schering-Plough Corporation in Support of its Motion to Dismiss to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

John R. Therien

# #16

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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|---|---|
| IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION | MDL NO. 1456 |
| THIS DOCUMENT RELATES TO: *County of Suffolk v. Abbott Laboratories, Inc., et al.* | CIVIL ACTION: 01-CV-12257-PBS<br>Judge Patti B. Saris |

**TAP PHARMACEUTICAL PRODUCTS INC.'S SEPARATE MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO DISMISS SUFFOLK COUNTY'S AMENDED COMPLAINT**

Suffolk County asserts claims against TAP Pharmaceutical Products Inc. ("TAP") as to only Prevacid®, a brand name drug used to treat gastrointestinal conditions. The allegations regarding Prevacid® are virtually non-existent, consisting only of a purported 28%-31% "spread" between Prevacid®'s AWP and a so-called "True AWP" calculated by Suffolk County. Am. Compl. ¶ 300. Otherwise, the only allegations made regarding TAP relate solely to Lupron®, a prostate cancer drug that is not a subject of this litigation and has no connection to Prevacid®. *See id.* ¶ 300.

The claims asserted against TAP by Suffolk County suffer from the same shortcomings as the claims asserted by the State of Montana in its Second Amended Complaint. The allegations asserted by Suffolk County against TAP track word-for-word many of the allegations raised by Montana. Therefore, TAP incorporates by reference its Individual Memorandum to Dismiss the State of Montana's Second Amended Complaint, filed with this Court on September 15, 2003 (hereinafter "TAP Mont. Mem."). Those arguments are summarized briefly below.

## I. Suffolk County Does not Identify Any Fraudulent Conduct as to Prevacid®

Suffolk County's shorthand contentions of fraud as to Prevacid® fall short of the pleading requirements set forth by the Court in *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 194 (D. Mass. 2003). Suffolk County identifies no conduct at all relating to Prevacid® beyond the publication of an AWP for that drug that exceeds by 28%-31% a number that Suffolk County contends is a "True AWP." Am. Compl. ¶ 300. Suffolk County never explains this so-called "True AWP." Instead, Suffolk County recites allegations about a guilty plea and settlement relating to Lupron® that have nothing at all to do with Prevacid®. As to its Best Price claims, Suffolk County alleges absolutely nothing regarding TAP. Am. Compl. ¶¶ 84-93.

These allegations are deficient and they fail to state a claim for the same reasons that identical allegations by Montana failed to state a claim. *See* TAP Mont. Mem. at 1-2. Accordingly, Suffolk County's claims against TAP should be dismissed.

## II. Suffolk County Does not Allege Any Competitor for Prevacid®

Suffolk County makes no allegations to show that TAP "marketed the spread" for Prevacid®. Am. Compl. ¶ 10. Indeed, Suffolk County does not even allege facts to show that TAP could have done so. Specifically, Suffolk County identifies no competitor for Prevacid®. Suffolk County also does not allege that the providers who prescribe Prevacid® would receive the profit from any alleged "spread."

In this regard, Suffolk County's Amended Complaint is deficient in the same way as Montana's Second Amended Complaint. *See* TAP Mont. Mem. at 2-3. As explained in TAP's motion to dismiss the Montana claims, plaintiff's theory of fraud requires competition. Without competition, manufacturers have no reason to manipulate AWPs, and the alleged scheme makes no economic sense. *See id.* Thus, because Suffolk County alleges no competitor for Prevacid®, the claims against TAP should be dismissed.

## III. Conclusion

For the foregoing reasons, as well as those stated in the defendants' consolidated memorandum and those individual defendants' memoranda that apply to TAP, this Court should dismiss Suffolk County's Amended Complaint as to TAP.

Respectfully Submitted,

Dated: September 15, 2003

Joseph F. Savage (BBO# 443030)
TESTA HURWITZ & THIBEAULT LLP
125 High Street
Boston, Massachusetts 02110-2704
Telephone: (617) 248-7000
Facsimile: (617) 790-0297

Daniel E. Reidy
JONES DAY
77 West Wacker Drive
Chicago, Illinois 60601
Telephone: (312) 782-3939
Facsimile: (312) 782-8585

***Counsel for Defendant***
***TAP Pharmaceutical Products Inc.***

# #17

**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

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|---|---|
| IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION | MDL No. 1456<br>Civil Action No. 01-CV-12257-PBS |
| THIS DOCUMENT RELATES TO:<br>*County of Suffolk v. Abbott Laboratories, Inc., et al.*, E.D.N.Y. Case No. CV-03-229 | Judge Patti B. Saris |

**MEMORANDUM OF WARRICK PHARMACEUTICALS CORPORATION IN SUPPORT OF THE MOTION TO DISMISS**

Warrick Pharmaceuticals Corporation ("Warrick") moves to dismiss Plaintiff's Amended Complaint ("Amended Complaint") pursuant to Fed. R. Civ. P. 12(b)(6) and 9(b). Plaintiff claims to have purchased only one Warrick drug, albuterol inhaler 90 MCG ("albuterol"). *See* Amended Complaint ¶¶ 4, 50, 75, 296 & App. A. First, as Plaintiff admits, Medicaid reimbursement for this drug is not based on AWP, but is instead subject to a Federal Upper Limit ("FUL"), *see id.*, which was first set in 1997. Plaintiff was on notice of any earlier AWP claims when they accrued, and the relevant limitations periods on any such claims expired long ago. Second, albuterol is a multi-source drug, and, as was the case for the Master Consolidated Class Action Complaint in this multidistrict litigation, "multi-source drugs do not fit the paradigm described in the complaint." *In re Pharma. Indus. AWP Litig.*, 263 F. Supp. 2d 172, 194 & n.11 (D. Mass. 2003). Finally, Plaintiff has failed entirely to satisfy the pleading requirements of Fed. R. Civ. P. 9(b) in connection with its allegations that Warrick reported "inflated AWPs," "fail[ed] to report Best Price," and offered "other inducements to stimulate the sales of [drugs]." Amended Complaint ¶¶ 87, 289, 291. For these reasons, as well as those stated in Defendants'

Memorandum of Law in Support of Their Motion to Dismiss the Complaint ("Joint Memorandum"), all of the claims against Warrick must be dismissed.

## ARGUMENT

### I. AWP Claims Prior to and During the Period When Albuterol Has Been Subject to a Federal Upper Limit Must Be Dismissed.

In October 1997, the Center for Medicare and Medicaid Services ("CMS"), pursuant to Medicaid regulations, first established a Federal Upper Limit on payments for albuterol.[1] New York Medicaid may not pay more for a prescribed drug than the FUL imposed by CMS. For a drug with an FUL, the federal government will reimburse the State no more than a reasonable dispensing fee plus an amount that is established by CMS that is equal to 150% of the published price for the least costly therapeutic equivalent that can be purchased in standard quantities (the FUL). 42 C.F.R. § 447.332(b). As Plaintiff admits, reimbursement of drugs for which an FUL has been established is thus *not based on AWP*. *See* Amended Complaint ¶ 75. All AWP claims relating to albuterol during the period when it was subject to an FUL must therefore be dismissed.[2]

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[1] *See* 42 C.F.R. § 447.332; *see also State Medicaid Manual*, HCFA Pub. 45-6, Transmittal No. 34, July 1, 1997 (setting upper limit on payment for Albuterol Sulfate 90 MCG, Solution, Aerosol Inhalation Refill 17 gm at $0.4394). Albuterol has been subject to various FULs. *See, e.g., State Medicaid Manual*, HCFA Pub. 45-6, Transmittal No. 35, July 1998 ($0.4394); *State Medicaid Manual*, HCFA Pub. 45-6, Transmittal No. 36, November 22, 2000 ($0.3490), *available at* http://www.cms.hhs.gov/medicaid/drugs/ful400.pdf.

[2] Plaintiff affirmatively alleges that albuterol was subject to an FUL in 2001, *see* Amended Complaint ¶ 75, even though the drug was temporarily removed from the FUL list in early 2001. *See* "Changes to Transmittal No. 36," *available at* http://www.cms.hhs.gov/medicaid/drugs/change36.asp (deleting "Albuterol, 0.09 mg/inh, Aerosol, Metered, Inhalation, 17gm" effective January 7, 2001) and "Changes to Transmittal No. 37" (adding "Albuterol, 0.09 mg/inh, Aerosol, Metered, Inhalation, 17gm" at $0.8823 effective March 11, 2003), *available at* http://www.cms.hhs.gov/medicaid/drugs/change37.pdf. Plaintiff also states a 2001 AWP for albuterol, *see* Amended Complaint ¶ 75 & App. A, but does not specify whether the FUL or the published AWP formed the basis for New York's reimbursement of albuterol that year. Plaintiff's contradictory allegations are insufficient under Fed. R. Civ. P. 9(b) to state an AWP claim for albuterol in 2001. Because the basis for reimbursement cannot be determined from the allegations, the Amended Complaint fails to state the requisite "who, what, where and how" of Warrick's alleged fraud, and does not provide adequate notice for Warrick to prepare a meaningful response. *See New England Data Servs. v. Becher*, 829 F.2d 286, 289 (1st Cir. 1987); *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 46 (D. Mass. 2001).

Any AWP claims that Plaintiff may have had prior to the establishment of an FUL for albuterol accrued, at the latest, in September 1997 – six years ago. None of the AWP claims Plaintiff seeks to bring has a limitations period that exceeds six years. *See Rotella v. Wood*, 528 U.S. 549, 552 (2000) (four year limitation period on claims under 18 U.S.C. § 1962(c)); *Gaidon v. Guardian Life Ins. Co. of Am.*, 96 N.Y.2d 201, 207-210 (2001) (three year period under N.Y. Gen. Bus. Law § 349; six year period for common law fraud); *Helfand v. Sessler*, 194 Misc. 2d 38, 40 (N.Y. Civ. Ct. 2002) (six year period for unjust enrichment). Plaintiff cannot bring a claim based on pre-1997 conduct relating to albuterol in this case.

Plaintiff attempts to avoid the statutes of limitations by alleging – generally – that defendants concealed the conduct that gave rise to Plaintiff's injuries. The claims are entirely devoid of detail as to Warrick, however, and therefore fail to meet the particularity requirement of Fed. R. Civ. P. 9(b). *See J. Geils Band Empl. Ben. Plan v. Smith Barney Shearson, Inc.*, 76 F.3d 1245, 1255 (5th Cir.) (holding that plaintiffs have the burden under Rule 9(b) to plead with particularity the facts giving rise to fraudulent concealment), *cert. denied*, 519 U.S. 823 (1996). More significantly, the New York Medicaid Program has known for decades that when States peg Medicaid reimbursement to AWPs, they frequently pay "in excess of actual acquisition cost to the retail pharmacist." 39 Fed. Reg. 41,480 (Nov. 27, 1974). For this reason, the federal government has repeatedly warned State Medicaid programs that they should "abandon the AWP reimbursement methodology." *Medicare Action Transmittal No. 84-72, reprinted in Medicare & Medicaid Guide* (CCH) ¶ 34,157 at 10,197 (1984). These public domain materials, and the numerous others available to Plaintiff and identified in the Joint Memorandum, are sufficient to defeat Plaintiff's fraudulent concealment claim. *See, e.g., In re Ultrafem Inc. Sec. Lit.*, 91 F. Supp. 2d 678, 692 (S.D.N.Y. 2000) (Bloomberg news article); *Blue Cross of California v.*

*SmithKline Beecham Clinical Labs., Inc.*, 108 F. Supp. 2d 116, 123-124 (D. Conn. 2000) (media stories and government reports).

**II. Plaintiff's AWP Claims Must Be Dismissed Under Fed. R. Civ. P. 9(b).**

In this multidistrict litigation, the Court has required plaintiffs to specify "the allegedly fraudulent AWP for each drug" in question. *In re Pharma. Indus. AWP Litig.*, 263 F. Supp. at 194. In Appendix A to the Amended Complaint, Plaintiff alleges only the 2001 AWP for albuterol, as well as a figure identified as "Suffolk's Estimated True AWP." *See* Amended Complaint ¶ 75 & App. A. Plaintiff offers no explanation of how it arrived at this "True AWP." The allegation is inadequate to meet the pleading requirements of Rule 9(b). Moreover, Plaintiff does not even purport to plead any albuterol AWP prior to the first establishment of an FUL for the drug in 1997. Thus, in addition to being barred by the applicable statutes of limitations, Plaintiff's AWP-based claims for that time period cannot satisfy Rule 9(b) and should be dismissed.

**III. Plaintiff's Multi-Source Generic Drug Claims Must Be Dismissed.**

For the same reasons that this Court dismissed the claims against multiple-source generic drugs in its May 13 Order, all claims relating to multi-source generic drugs – including Warrick's albuterol – should be dismissed. *See In re Pharma. Indus. AWP Litig.*, 263 F. Supp. 2d at 194 & n.11. In duplicating the private class action plaintiffs' theory for generic drugs, Plaintiff has duplicated its fatal flaws. *Compare* Amended Complaint ¶¶ 97-99 to Amended Master Consolidated Class Action Complaint ¶¶ 186-188. Plaintiff has failed entirely to fit the generic market into the paradigm of fraudulent conduct alleged throughout the Amended Complaint. New York State Medicaid pays the same amount for all formulations of a multi-source drug, regardless of which pharmaceutical company makes it. Under this reimbursement

scheme, no manufacturer can obtain a competitive advantage or an increased market share based on its own published AWP. Plaintiff therefore fails to set forth any meaningful AWP-based allegations against Warrick's albuterol, and the claims must be dismissed.

## IV. Plaintiff's Allegations Concerning Best Price Reporting and "Other Inducements" Must Be Dismissed.

Finally, the broad, general allegations that the defendants "routinely do not report the actual 'best price,'" and "utilized an array of other inducements to stimulate sales of their drugs" are wholly without substance and should be dismissed in their entirety. *See* Amended Complaint, ¶¶ 84-90, 290-292. Plaintiff fails to provide a *single specific example* of a failure by Warrick to report its statutory best price to CMS, or of any "other inducements" allegedly offered by Warrick to providers. These claims fail to state the requisite "who, what, where and how" of Warrick's alleged fraud, s*ee United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 46 (D. Mass. 2001) (*quoting United States ex rel. Thompson v. Columbia/HCA Healthcare*, 125 F.3d 899, 903 (5th Cir. 1997)), and are insufficient under Rule 9(b) to "place [Warrick] on notice and enable [it] to prepare meaningful responses." *New England Data Servs. v. Becher*, 829 F.2d 286, 289 (1st Cir. 1987).

## CONCLUSION

For the foregoing reasons, as well as those stated in the Joint Memorandum in Support of Defendants' Motions to Dismiss, Warrick requests that it be dismissed from the Amended Complaint.

Respectfully Submitted,

Original Signature On File With Court

/s/ John T. Montgomery /JRT

John T. Montgomery (BBO#352220)
Brien T. O'Connor (BBO#546767)
Crystal D. Talley (BBO#633759)
John R. Therien (BBO#651185)
Ropes & Gray LLP
One International Place
Boston, Massachusetts 02110-2624
(617) 951-7000

Dated: September 15, 2003

CERTIFICATE OF SERVICE

I hereby certify that on September 15, 2003, I caused a true and correct copy of the Memorandum of Warrick Pharmaceuticals Corporation in Support of its Motion to Dismiss to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

John R. Therien

# #18

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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| IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION | MDL NO. 1456 |
| | CIVIL ACTION: 01-CV-12257-PBS |
| THIS DOCUMENT RELATES TO: | Judge Patti B. Saris |
| COUNTY OF SUFFOLK v. ABBOTT LABORATORIES, INC. et al., Civil Action No. 03-10643-PBS | |

**DEFENDANT WYETH'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS THE AMENDED COMPLAINT**

## INTRODUCTION

Wyeth, by and through its undersigned counsel, hereby submits this Memorandum in Support of the Motion to Dismiss the Amended Complaint. Wyeth adopts and incorporates by reference the arguments set forth in the Consolidated Motion to Dismiss Amended Complaint and Supporting Memorandum of Law. In addition, for the reasons set forth below, the claims against Wyeth must be dismissed because the Plaintiff has failed to comply with the heightened pleading standard of Federal Rule of Civil Procedure 9(b) and the pleading requirements set forth in this Court's Memorandum and Order dated May 13, 2003 ("May 13 Order").

The 131-page Amended Complaint wholly fails to meet these pleading requirements. Plaintiff's claims are based generically on the allegation that the Defendants engaged in a "fraudulent scheme with others in the pharmaceutical distribution chain . . . to collect inflated prescription drug payments" from Plaintiff. Amended Complaint at ¶ 2. Of the 419 numbered paragraphs in the Amended Complaint, only six refer to Wyeth.[1] Each fails to describe with any particularity Wyeth's purported role in any alleged fraudulent scheme or to state with particularity a single fraudulent statement or action by Wyeth.

## ARGUMENT

### I. Plaintiff's Allegations Against Wyeth Fail for Lack of Particularity.

Federal Rule of Civil Procedure 9(b) provides that "in all averments of fraud . . . the circumstances constituting the fraud . . . shall be stated with particularity." Particularly in a RICO case, the First Circuit has cautioned that "[d]ue to the potency of RICO allegations, 'particular care is required to balance the liberality of the Civil Rules with the necessity for preventing abuse or vexatious treatment of the defendants.'" *Bowdoin Constr. Corp. v. Rhode Island Hosp. Trust Nat'l. Bank*, 869 F. Supp. 1004, 1006 (D. Mass. 1994) quoting *Miranda v.*

[1] Wyeth is not a defendant in the Consolidated Amended Class Action Complaint.

*Ponce Fed. Bank*, 948 F.2d 41, 44 (1st Cir. 1991). Simply put, Rule 9(b) requires that a plaintiff plead the "who, what, where, and how" of the alleged fraud. *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 46 (D. Mass. 2001).

Plaintiff's allegations as to Wyeth are perfunctory at best and thus fail this test. Plaintiffs simply state that Wyeth reported "false and inflated" AWPs for its products Protonix and Effexor. Amended Complaint at ¶ 311. The sole detail with respect to this allegation consists of a chart indicating a variance or "spread" between the reported AWP and Plaintiff's "Estimated True AWP." The "spread" alleged by Plaintiff is 3% for Effexor and 26% for Protonix. The Complaint provides no detail as to how the alleged "Estimated True AWP" was calculated, e.g., which sales were included in the calculation, whether it is a simple or weighted average, what its margin of error is, etc.

These defects are particularly glaring with respect to the alleged 3% "spread" between reported AWP and "estimated true AWP" for Effexor. Plaintiff's allegations in this regard are most curious. Plaintiff concedes, as it must, that the New York Medicaid program was aware that AWP is not a representation of actual acquisition costs and that this knowledge was reflected in the 2002 Medicaid reimbursement rate of AWP minus 10%. Amended Complaint at ¶ 73. Apparently Plaintiff is alleging that the AWP for Effexor was "fraudulent" even though the New York Medicaid program, according to Plaintiff's own calculations, reimbursed providers 7% less than their actual acquisition cost for the drug.

The alleged "false" AWP for Protonix varies from the alleged "Estimated True AWP" by 26%. Even if one accepts Plaintiff's calculations, it is unclear how such a variance would constitute fraud in view of the fact that this percentage closely approximates the variances between published AWPs and actual sale prices found in numerous government reports that were

well known to the New York Medicaid Program. Amended Complaint at ¶ 73; see also Defendant's Consolidated Memorandum of Law at pages 5-10.

With respect to other "Covered Drugs," Plaintiff's complaint lacks even these cursory allegations, and simply states that "similar" practices resulted in "comparable damage" for all Covered Drugs. This allegation as to unnamed "Covered Drugs" is clearly insufficient to meet the pleading requirements set forth in this Court's Memorandum and Order dated May 13, 2003.

The RICO allegations are similarly deficient. The Amended Complaint here relies exclusively upon conclusory, general statements to describe Wyeth's alleged "Manufacturer-Publisher Enterprises." Amended Complaint at ¶ 341 (cc). Indeed, except for the name of the Defendant, allegations about Wyeth's operation of these enterprises and pattern of racketeering activity are identical to those allegations stated against others, and merely mimic the statutory language concerning the prerequisites of RICO allegations. Similarly, Plaintiff's charges of mail and wire fraud by Wyeth are based upon general allegations collectively asserted against all Defendants. Amended Complaint at ¶ 342. Likewise, Plaintiff's allegations relating to the guilty pleas and government investigations of other Defendants to this action do not satisfy the requirements of Rule 9(b) with respect to Plaintiff's claims against Wyeth. Instead of particularizing Wyeth's role, the Plaintiff attempts to paint Wyeth and all other defendants with broad assertions of wrongdoing.

This Court and Rule 9(b) require more. *Reves v. Ernst & Young*, 507 U.S. 170, 184 (1993) (affirming dismissal of complaint where plaintiff failed to allege with specificity how defendant participated in the operation or management of the alleged enterprises). *See Suna v. Bailey Corp.*, 107 F.3d 64, 68 (1st Cir. 1997) (requiring plaintiffs to explain why statements were fraudulent); *United States ex rel. Gublo v. NovaCare, Inc.*, 62 F. Supp. 2d 347 (D. Mass. 1999)

(dismissing under Rule 9(b) Medicare fraud case because plaintiff failed to allege why or how the defendant's price representations were fraudulent). *See also Curtis v. Duffy*, 742 F. Supp. 34, 38 (D. Mass. 1990) ("[I]t is not enough to salt the complaint with the words 'falsely' and 'fraudulently'"). Plaintiffs fail to particularize Wyeth's role in any of these alleged violations and therefore claims also should be dismissed based on Rule 9(b).

## CONCLUSION

For the foregoing reasons, and for the reasons set forth in the Consolidated Memorandum, Wyeth requests that the Amended Complaint against it be dismissed.

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S. Craig Holden
Connie E. Eisman
Ober, Kaler, Grimes & Shriver
A Professional Corporation
120 East Baltimore Street
Baltimore, Maryland 21202-1643
(410) 685-1120
(410) 547-0699

James C. Burling
Edward E. Hale
Hale & Dorr LLP
60 State Street
Boston, Massachusetts 02109
(617) 526-6000
(617) 526-5000

Attorneys for Defendants